

Nestlé USA



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March 31, 2006

Tomoko Shimakawa
Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
5100 Paint Branch Parkway, HFS-830
College Park, MD 20740-3835

Re: Docket 2005Q-0298 – Petition for Qualified Health Claim for
100% Whey Protein, Partially Hydrolyzed, in Infant Formula and
Reducing the Risk of Allergy in Infants

Dear Ms. Shimakawa:

I am writing to address the recent Canadian Broadcasting Corporation (CBC) broadcast featuring Dr. Ranjit Chandra, which was mentioned in another recent comment to this docket. Nestlé does not wish to comment on the accusations against Dr. Chandra or his research, as they have not been verified, and we will trust the university and the peer reviewed journals concerned to either affirm or retract the research. We continue to believe in the scientific community's peer review process and its ability to validate research efforts.

As you will have already seen during your review of this petition, the claims supporting the efficacy of 100% whey protein, partially hydrolyzed formula (PHF-W) from Nestlé in reducing the risk of allergies are based on a large body of clinical evidence. Independent of Dr. Chandra's single study, clinical trials by other independent researchers in 11 separate and independent subject cohorts, reported in 15 peer reviewed publications, constitute the supportive evidence for this petition regarding efficacy of PHF-W in allergy risk reduction. And Dr. Chandra's study results are consistent with the findings of the other clinical trials investigating this efficacy.

However, until such time as the current controversy surrounding the integrity of Dr. Chandra's research has been resolved, we have chosen to suspend references to his work in our educational and scientific materials. By this letter, we wish to inform the FDA of Nestlé's knowledge of the events surrounding the controversy, and to advise that we will keep the agency informed of any developments of which we become aware.

Nestlé was aware of, and cooperated fully with, a formal investigation into Dr. Chandra's work that was conducted by Memorial University between 1994 and 1996. This investigation called into question studies done by Dr. Chandra between 1987 and 1992, including clinical trials

examining the incidence of allergy in infants fed formulas from various manufacturers including Nestlé. In 1996, Nestlé was notified by the University President that the investigation had been closed and that no further action would be taken against Dr. Chandra (see attached copies of the 1996 correspondence). Subsequently, in 1997, the 5-year results of one of the studies in question were published in the peer-reviewed Journal of Pediatric Gastrointestinal Nutrition (JPGN).

Companies often work and collaborate with independent researchers at reputable universities in order to conduct research into potential new products and benefits. In many cases, as with Dr. Chandra's allergy prevention study with Nestlé PHF-W, the university will receive a grant to fund clinical trials, the research is conducted independently, and the company does not control the results. In the case of Dr. Chandra, Nestlé relied on both Memorial University and the peer-review publication process, to validate his data and conclusions. Nevertheless, at the time of the investigation, Nestlé decided that any reference to Dr. Chandra's research would thereafter be made only as part of the complete body of evidence. Nestlé has not conducted any research with Dr. Chandra since the 1997 report of that study was published in JPGN.

Because Nestlé does not rely on any one study to substantiate our infant formula product benefits, the CBC program does not change the conclusion from the substantiation included in our petition. Dr. Chandra's research is mentioned in several scientific reviews and summaries, some of which appear in the petition. Additionally, two meta-analyses have included Dr. Chandra's research—notably Baumgartner (1998) and the Cochrane Library (2004)—both of which appear in the petition. However the body of evidence in this area is sufficiently strong and consistent that, even if Dr. Chandra's studies were removed from these analyses, the conclusions would not be expected to change. As long as the peer reviewed journals continue to uphold the publication of these clinical trials, it is likely that others will continue to reference them.

In summary, one of the clinical trials done by Dr. Chandra which is being questioned, was part of the early research into the allergy prevention benefits of PHF-W. Since this 1989 study, an additional 15 clinical trial reports consistent with these early findings have been published. Thus, regardless of whether Dr. Chandra's study is ultimately found to be valid or not, there is ample support without it for the role of 100% Whey Protein, Partially Hydrolyzed, in Infant Formula in Reducing the Risk of Allergy in Infants.

Please file a copy of this letter in the administrative docket as noted above.

Yours truly,

A handwritten signature in black ink, appearing to read "Saavedra", with a stylized flourish at the end.

José M. Saavedra, M.D.
Medical and Scientific Director
Nestlé Nutrition

cc: Fred Degnan – King & Spalding



Memorial

University of Newfoundland

Office of the Vice-President (Academic)
and Pro Vice-Chancellor

1996 02 12

Mr. Stephen Allen
Vice-President, Nutritional Products
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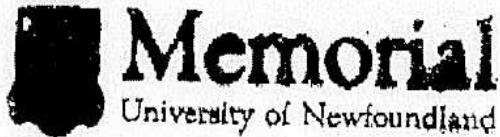
Dear Mr. Allen:

This is further to our letter dated April 22, 1994 advising that the University was in receipt of a complaint of scientific fraud against Dr. R. K. Chandra concerning the Carnation study published in the *Annals of Allergy* 1989 and the 18-month follow-up (published in the *Annals of Allergy* 1991) and the three and five year follow-up studies. We wish to inform you that the investigation into the complaint has now been closed and the University will not be taking any further action on this matter.

Thank you for your cooperation throughout the investigation process.

Yours sincerely,

J. Tuinman
Vice-President (Academic)
and Pro Vice-Chancellor



Office of the President and Vice Chancellor

January 23, 1996

Dr. R.K. Chandra
Janeway Child Health Centre
St. John's, NF
A1A 1R6

Dear Dr. Chandra:

Please be advised that the University has decided to close its investigation into the complaints against you as set out in the 31 January, 1994 letter of Dr. Albert J. Davis. The evidence which the University has been able to gather through its investigative process is not sufficient to warrant further action against you relating to the Carnation Study and the three and five year follow up studies.

The University will, of course, proceed to notify all those organizations and persons contacted during the investigative process to advise them of the disposition of the investigation. At your convenience, we will arrange the release to you of those files which were secured by the University during this process.

Thank you for your cooperation throughout.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "A.W. May", written over a horizontal line.

A.W. May
PRESIDENT AND VICE-CHANCELLOR

AWM/pcc

- cc: - Dr. J. Tuinman
- Dr. K. Keough
- Mr. W.W. Thisle
- Dr. I. Bowmer